REMARKS

The Examiner has noted that the number of one of the references cited in the international search report was incorrectly transcribed to the information disclosure statement. The correct US patent number is 6,075,369 (Morgan). A supplemental information disclosure statement is included with this correct number.

Claims 1, 3, 4, 14 and 22 were rejected under 35 U.S.C. §102(b) as being anticipated by US Pat. 3,805,795 (Denniston et al.) and Claims 5, 8, 19 and 20 were rejected under §103(a) as being rendered unpatentable by Denniston et al. alone. The ingenuity of the Examiner in finding and applying this reference to the pending claims is commendable. However, applicants respectfully disagree with the conclusion that this reference alone or in combination with others renders the present claims unpatentable.

Pending Claim 1, which is representative of the present invention, describes an apparatus for detecting at least one of handling of electrodes and removing of the electrodes from a package comprising a pair of electrodes suitable for attachment to a patient and each including a conductor for sensing a patient electrical characteristic or delivering electricity to a patient; an impedance element included with at least one of the electrodes which varies when an electrode is flexed or bent; a current delivery circuit, coupled to the electrodes, which causes current to flow through the impedance element; a monitoring circuit coupled to the impedance element for monitoring a magnitude of an electrical characteristic resulting from the flow of current through the impedance element, wherein an occurrence of at least one of handling and removing of the electrodes is identified by the variation of the impedance of the impedance element. An automated defibrillator such as an AED which may be used by a layperson rescuer always presents the challenge of

trying to automatically assess what the rescuer is doing so that the defibrillator can monitor the progress of the rescue and offer appropriate assistance as by verbal prompts. By monitoring changes in the impedance of an impedance element which varies when an electrode is flexed or bent, the AED can deduce whether the rescuer has opened the electrode package and applied the electrodes to the patient. If the impedance characteristic indicative of these actions is not observed, the AED can offer more detailed instruction to assist in a successful rescue where time is of the essence. The detailed description of the present application gives examples of impedance variations which are indicative of these actions by a rescuer and can be automatically recognized by a defibrillator.

Denniston et al. describe an implantable defibrillator which is trying to discern when a patient's heart has stopped beating. When this happens, the implanted defibrillator applies a shock or series of shocks to restart the heartbeat. Denniston et al. monitor what they call "two dynamic characteristics" of the heart to detect this condition. The presence of the two indicate that the heart is beating and the absence of both indicate that the heart has stopped. One of these characteristics is the patient's electrical EKG signal which is obtained from electrodes on an intravascular lead which is placed in the patient's heart chamber. The other characteristic is the physical contraction and relaxation of the heart muscle which is detected by an elastomer body which changes impedance when flexed by the contracting heart muscle. How the two sensors for these characteristic are configured is not clear, as Denniston et al. represent them both by an electrical lead box 16. Denniston et al. do say that the heart muscle contraction detector is a conductive elastomer body having carbon particles imbedded in it. The elastomer body is operated by continually applying a 4 volt power source to it and observing electrical change at a circuit junction 113. This

patent teaches that the contraction of the heart can be detected by a variable impedance device placed inside the heart which is flexed by the contracting heart.

It is respectfully submitted that this does not suggest using a variable flexed or bent impedance device to determine whether a rescuer has opened a defibrillator electrode package or handled the electrodes to apply them to a patient. The only commonality between Denniston et al. and the present invention is that they both involve defibrillation and they both use an impedance element which varies when flexed or bent. Neither patent or application suggests the distinctly different purpose of the other. One faced with the challenge of assessing whether a rescuer has handled or opened an electrode package would not look to an intravascular lead which detects heart contractions. It is respectfully submitted that only the present application provides the incentive for considering a variable impedance element to look for electrode handling by a rescuer. For these reasons it is respectfully submitted that Denniston et al. cannot anticipate Claims 1, 3-5, 8, 14, 19, 20 and 22 or render them obvious.

Claims 6, 21, and 23 were rejected under 35 U.S.C. §103(a) as being unpatentable over Denniston et al. in view of US Pat. 4,706,680 (Keusch et al.) Keusch et al. was cited for its teaching of using hydrogel with defibrillation electrodes. However Keusch et al. fails to show or suggest using the variable impedance of an element with an impedance that varies when flexed or bent to discern that a rescuer has opened an electrode package or handled the electrodes. Accordingly it is respectfully submitted that the combination of Denniston et al. and Keusch et al. cannot render Claims 6, 21 and 23 or the base claims from which they depend unpatentable.

In view of the foregoing remarks it is respectfully submitted that Claims 1, 3-5, 8, 14, 19, 20 and 22 are not anticipated by and are patentable over Denniston et al. It is further respectfully submitted that Claims 6, 21 and 23 are patentable over the combination of Denniston et al. and Keusch et al. Accordingly it is respectfully requested that the rejection of Claims 1, 3, 4, 14 and 22 under 35 U.S.C. §102(b) and of Claims 5, 6, 8, 19, 20, 21 and 23 under 35 U.S.C. §103(a) be withdrawn.

In light of the foregoing it is respectfully submitted that this application is now in condition for allowance. Favorable reconsideration is respectfully requested.

Respectfully submitted,

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